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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,956	10/10/2001	Xuehai Ye	64688/152	6226

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4329 Van Ness St., NW
Washington, DC 20016-5625

EXAMINER

ANGELL, JON E

ART UNIT	PAPER NUMBER
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1635

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DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,956

Applicant(s)

YE ET AL.

Examiner

J. Eric Angell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10-10-01 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Action is in response to the communication filed on 1/22/03, as Paper No. 10. The amendment has been entered. Claims 1 and 2 have been amended. New claims 13-17 have been added. Claims 1-17 are currently pending in the application and are addressed herein.

Election/Restrictions

2. Newly submitted claim 17 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 17 is an invention drawn to an animal model, while claims 1-16 are drawn to an invention that is a method of transferring a gene or genes of interest into glomerular cells of the kidney. The inventions are unrelated for the following reasons. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation, different functions and different effects. The Invention of claim 17 is an animal that can be used for testing the efficacy/efficiency of a gene transfer method, while the invention of claims 1-16 is a gene transfer method. The modes of operation, functions and effects of the two inventions are different because the function and effect of the animal is to test efficacy/efficiency of gene transfer, while the function and effect of the gene transfer method is to transfer a gene/genes of interest into target cells of the kidney. Furthermore, the method could be used for different purposes, other than testing efficacy of gene transfer in an animal model. For instance, the gene transfer method could be used to transfer a therapeutic gene into diseased glomerular cells for gene therapy, or simply to mark target cells

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(glomerular cells) with a reporter gene (such as lacZ or GFP) so that the glomerular cells can be visualized for developmental or histological studies. Therefore, the different methods have different modes of operation.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 17 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 101

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12 remain rejected and new claims 13-16 are under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 1-16 are drawn to a method for infecting the glomerular cells of the kidney of a mammalian subject with a recombinant adenovirus vector carrying a gene or genes of interest.

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New claims 13-16 only specify the gene of interest that is transferred. Therefore, the claims are rejected under 35 USC 101 for the reasons of record.

Claim Rejections - 35 USC § 112

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-12 remain rejected and new claims 13-16 are under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial and well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claims 1-16 are drawn to a method for infecting the glomerular cells of the kidney of a mammalian subject with a recombinant adenovirus vector carrying a gene or genes of interest. New claims 13-16 only specify the gene of interest that is transferred. Therefore, the claims are rejected under 35 USC 112, first paragraph, in view of the rejection under 35 USC 101 for the reasons of record.

Response to Arguments

6. Applicant's arguments filed 1/22/03 have been fully considered but they are not persuasive.

7. Applicants argue that gene therapy is not the subject of the claimed invention. Rather, Applicants indicate that the utility of the present invention lies in the creation of an animal model for the evaluation of the efficacy/evaluation of gene vectors and other agents used for treating

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renal glomerular diseases, and to produce animal models (see pages 3-4 of the response filed 1/22/23). Applicants contend that the invention has at least one specific, substantial and credible utility. Applicants point to two publications as evidence that the claimed invention has patentable utility (see bottom of page 4). Furthermore, Applicants have submitted affidavits or declarations from experts in the art to demonstrate that one of ordinary skill in the art would have considered an animal model credible for the avowed purpose at the time the application was filed (see p. 5, and the Declarations of Dr. Batshaw and Dr. Newman).

8. In response to Applicants' argument that the asserted utility of the invention is as an animal model for testing the efficacy/efficiency of gene transfer, it is respectfully pointed out that the Utility guidelines indicate,

“Materials to be used for research, or methods of using those materials for research, raise issues of whether the utilities require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use. See, e.g., Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Supp. Ct. 1966) wherein a research utility was not considered a “substantial utility.”

And

“Utilities that require or constitute carrying out further research to identify or reasonably confirm a “real world” context of use are not substantial utilities.” (See Utility Guidelines, pages 4 and 6).

9. In the instant case, the claims encompass a method of transferring a gene/genes of interest to renal glomerular cells. Applicants argue that the claimed invention has utility as an animal model for testing the efficacy/efficiency of gene transfer methods. However, an animal model to test the efficacy/efficiency of gene transfer clearly requires further research. Specifically, further testing is required to identify or reasonably confirm the efficacy/efficiency of the transfer method. Therefore, the claimed invention lacks patentable utility because there is no

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substantial or “real world” use for the invention. The submitted abstract cited in the response also clearly indicates that the method can be used as a tool to study the effect of foreign gene expression on the structure and function of rat renal glomeruli, in vivo. This only indicates that the method can be for used further research and testing—which does not constitute a substantial, “real world” use for the method. Regarding the Declarations of Drs. Batshaw and Newman, under 37 CFR 1.132 filed 1/22/03 is insufficient to overcome the rejection of claims 1-16 based upon 35 USC 101 and 112, first paragraph as set forth in the last Office action because: the declarations are only the opinions of the declaring parties and do not overcome the rejections summarized above, because they do not offer evidence indicating that there is a substantial, “real world” use for the invention (i.e. the declarations do not indicate that the method can be used without further research/experimentation). Furthermore, the specification, references cited in Applicants arguments, and the Applicants arguments themselves assert that the only use for the claimed method is for further testing in animal models—clearly indicating that further research is required. Therefore, the claims are rejected for the reasons of record and summarized above.

10. Regarding the rejection of claims under 35 USC 112, first paragraph, in view of the utility rejection, Applicants argue that the invention has credible, specific and substantial utility, and the animal model which can be used for testing the gene transfer method has been adequately described (see pgs. 5-6). Applicant's arguments have been fully considered but they are not persuasive. The claims remain rejected under 35 USC 101 for not having a substantial, “real world” use, for the reasons of record and above. Therefore, without a substantial/“real

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world" use, one of ordinary skill in the art would not know how to make/use the invention without performing additional experimentation.

Conclusion

No claim is allowed.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is (703) 605-1165. The examiner can normally be reached on M-F (8:00-4:30).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

J. Eric Angell, Ph.D.
April 4, 2003



DAVE T. NGUYEN
PRIMARY EXAMINER